Pneumex
Try Something Pneu...

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Dockets Management Branch
HFA-305, Food and Drug Administration
Dept. of Health and Human Services
Room 1-23, 12420 Parklawn Drive
Rockville, MD 20857

CC To
CDRH's Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850.

April 11, 2008

Citizen Petition
The undersigned submits this petition under Class II 510(k) exemption petition of the Section 206 of the FDA Modernization Act of 1997 to request the Commissioner of Food and Drugs to exempt class II device types, as defined in 21 CFR 860.3, from the pre-market notification requirements of section 510(k) of the Act. II.

Device classification name: Vibro-Trac
Regulation number: NA
Gerry Cook
2605 North Boyer Ave
Sandpoint, ID 83864
208-265-4105
208-265-9651

(1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials; The Vibro-Trac table is combining two technologies which have been in the rehabilitation industry for a number of years. Neither intermittent traction nor vibration has a significant history of false or misleading claims or risks to the patient associated with inherent characteristics associated with either type of device.

(2) Characteristics of the device necessary for its safe and effective performance are well established; We have been using intermittent traction for 15 years and vibration for seven years in our equipment and have an excellent understanding of design parameters necessary for safe and effective performance.

(3) Changes in the device that could affect safety and effectiveness: The Vibro-Trac is designed to provide a safe, noninvasive treatment. It is a mechanical device with multiple layers of back up systems to minimize or eliminate risk to user. (UL, CE etc certification) The table portion is tested to more than 400 lbs and is stable, tip resistant

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and will not shift or suddenly drop if power is cut. The vibration portion is regulated by an operator and can not accidentally be increased in intensity or speed. At the highest intensity and speed it is safe for everyone except persons just out of surgery. The intermittent traction portion is controlled by an operator and is designed to slowly increase and decrease traction. If power or air pressure should fail the traction portion will slowly return to a neutral state.

(4) Any changes to the device would not be likely to result in a change in the device's classification: No changes are contemplated which would change the classification.

Pneumex is petitioning for the reclassification of the equipment designed by Pneumex known as the Pneu-Vibe Vibro-Trac. It is requested that Pneu-Vibe Vibro-Trac be classified to Class II exempt. We base this request on the classification of its parts, table, vibration and intermittent traction. All exempt.

Regulation Description	Powered table.
Product Code	INQ
Submission Type	510(k) Exempt
Regulation Number	890.3760

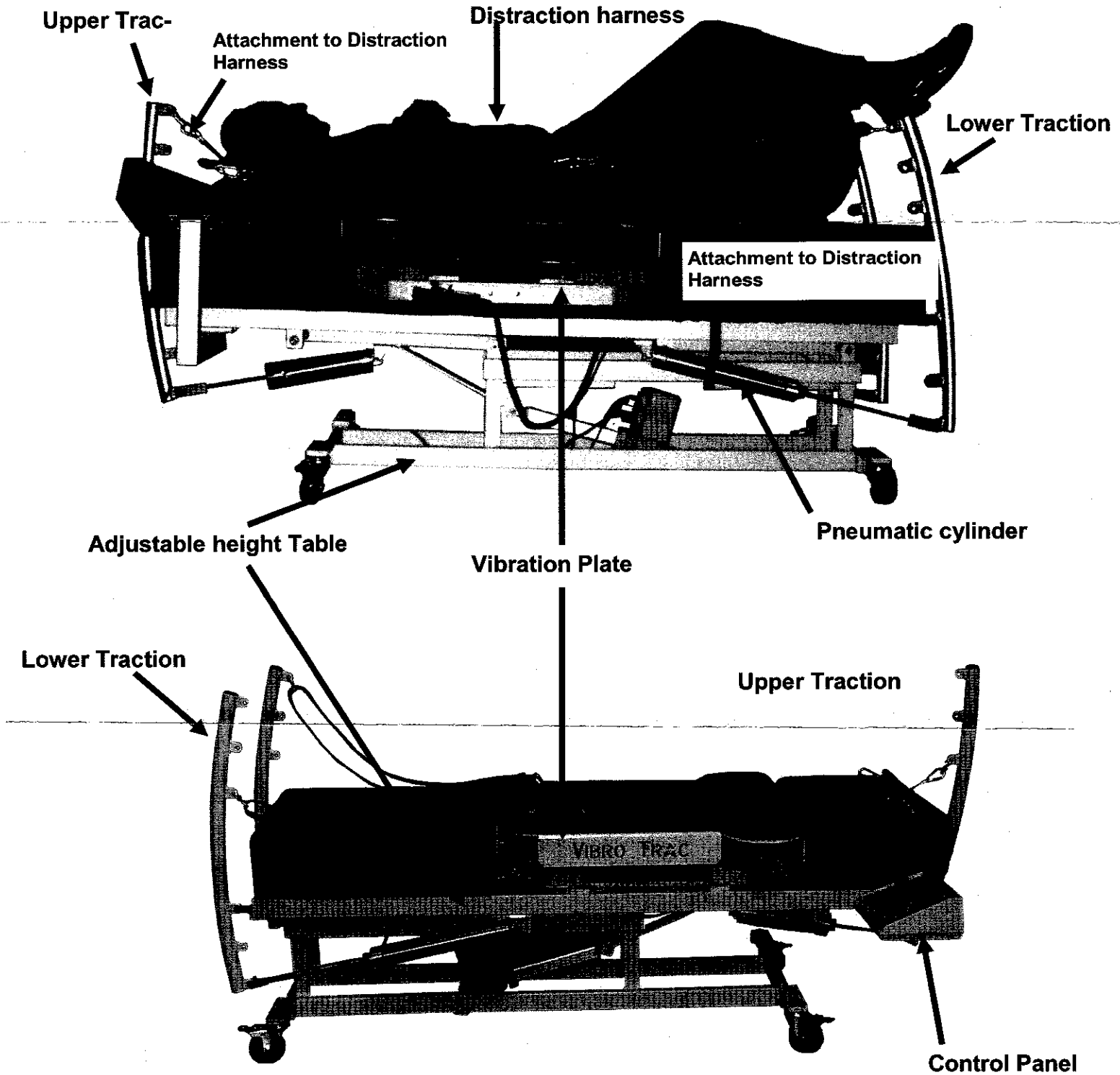
Regulation Description	Therapeutic vibrator.
Product Code	IRO
Submission Type	510(k) Exempt
Regulation Number	890.5975

Regulation Description	Traction accessory.
Product Code	ILZ
Submission Type	510(k) Exempt
Regulation Number	890.5925

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Gerry Cook
2605 North Boyer Ave
Sandpoint, ID 83864

Pneumex, Inc
Vibro-Trac 2008



May 2, 2008

Division of Dockets Management, Food and Drug Administration, Department of Health and Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Citizen Petition
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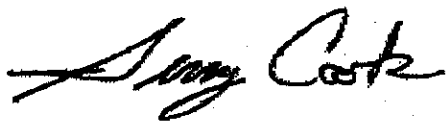
Device classification name: Vibro-Trac
Regulation number: NA

Claim for categorical exclusion under Title 21--Food and Drugs ,Chapter 1--Food and Drug Administration Department of Health and Human Services ,Subchapter A—General, Part 25 – Environmental Impact Considerations, Subpart C—Categorical Exclusions Sec. 25.30 General

The Vibro-Trac has no negative impact on the environment. It is not made of materials considered to be toxic or flammable. Biological tissues, cells or body fluids are not influenced when used as for the intended purpose. The Vibro-Trac produces no radiation or chemical reactions.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



Gerry Cook

2605 North Boyer Ave
Sandpoint, ID 83864
208-26+5-4105

04398 MAY -5 A6:36

Pneumex Try Something Pneu... **FAX** *"Try something Pneu..."*	**From:** **Pneumex, Inc.,** 2605 North Boyer Ave Sandpoint, Idaho 83864 E-Mail pneumex@pneumex.com **Tonnie Hoisington**
TO: Lyle Jaffe	**DATE:** 05-02-08 **Number of pages including cover sheet:** 2
RE: ENVIronmental Impact	**Copy to:** Gerry Cook
Phone:	**Phone:** (208) 265-4105 **(800) 447-5792**
Fax Phone: 301-827-6870	**Fax Phone:** (208) 265-9651

REMARKS: Urgent (For your review) Reply ASAP Please Comment

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ROCKVILLE, MD 20857